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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,157	07/24/2001	Scott R. Presnell	00-49	3977

7590 05/30/2003

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EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Rule copy

Office Action Summary	Application No.	Applicant(s)	
	09/912,157	PRESNELL ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-3 and 13-24* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detail d Action

1. Receipt of Applicants' amendment filed on 07 April 2003 in Paper No.11, is acknowledged. Claims 4-12 have been canceled without prejudice and new claims 18-24 have been added.

Election/Restriction

2. Applicant's election with traverse of the invention of Group II (claims 4-12, (canceled), new claims 18-24), and the species of the polypeptide of SEQ ID NO:2, in Paper No. 11, filed on 07 April 2003 is acknowledged.

Applicants' first ground of traversal is that the invention as claimed can be readily evaluated in one search without placing undue burden on the Examiner. Applicants' second traversal is that the commissioner has partially waived the requirement of 37 C.F.R 1.141 and will permit a reasonable number of nucleotides to be claimed in a single application. Finally, Applicants' third ground of traversal is that species of SEQ ID NO:1 and SEQ ID NO:2 are patentably indistinct.

Applicants' grounds of traversal have been fully considered but are not deemed persuasive. With respect to Applicants' first ground of traversal, the claims of the instant application are drawn to patentably distinct inventions and species as was explained in the office action mailed on 10 February 2003, in paper No:7. Contrary to Applicants' assertion a single search would not reveal art pertinent to all of the recited inventions. Thus, searching more than one product would pose undue burden on the Examiner.

With respect to Applicants' second ground of traversal, although it is accurate that the commissioner has partially waived the requirement of 37 C.F.R 1.141 and will permit a reasonable number of nucleotides to be claimed in a single application, this waiver is not applicable to the instant application for the following reason: nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121, (see MPEP 2434). Absent evidence to the contrary, each such nucleotide sequence is presumed to

represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

With respect to Applicants' last traversal, it was explained in the office action mailed on 10 February 2003, in paper No:7, why a nucleic acid and the encoded polypeptide are distinct inventions. The polypeptide of SEQ ID NO:2 and the nucleic a cid of SEQ ID NO:1 are products which possess characteristic differences in structure and function and each has an independent use, that is distinct for each invention which cannot be exchanged. The nucleic acid can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. Furthermore, the polypeptide of SEQ ID NO:2 and the nucleic acid of SEQ ID N O:1 are classified in different classes and sub-classes and each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. (MPEP § 808.02).

The requirement is still deemed proper and is therefore made FINAL.

Claims 18-24 will be searched and examined since they are drawn to the elected inventions.

Claims 1-3, 13-17 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested "nucleic acid encoding human cytokine receptor".

Claim Rejections - 35 U.S.C. § 101/112

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5a. Claims 18-24 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 18-24 of the instant invention are directed to an isolated nucleic acid encoding a polypeptide that comprises of amino acid residues 36-313, 336-753, 36-753 and 1-753 of SEQ ID NO:2, a vector comprising said nucleic acid, a recombinant host cell comprising said vector and a method of producing the encoded protein.

The specification describes the claimed nucleic acid as encoding a novel receptor designated as "Zcytor18" (see page 2, lines 7-11). Instant specification states that the Zcytor18 gene is strongly expressed in testicular, ovarian and uterine tissue and moderately expressed in fetal heart, fetal bladder, fetal kidney, fetal skin and adult brain, (see page 3, lines 3-11). The specification also states that the Zcytor18 gene is higher in breast tissue than in normal breast tissue and that it can be used to differentiate tissues, (see page 3, lines 10-11).

However, instant specification does not disclose any information regarding physiologic or functional characteristics of the protein encoded by the claimed nucleic acid. Furthermore, the polypeptide encoded by the claimed nucleic acid has never been expressed, no biological activity was assayed or determined for it, its endogenous ligand is not identified and only a deduced amino acid sequence and general methods of expressing recombinant proteins is disclosed. Instant specification asserts that the polypeptide encoded by the claimed nucleic acid can be used; to generate antibodies (page 37, lines 6-10), to identify and isolate Zcyor18 ligands,(page 50, lines 34-37), to differentiate tissues, to modulate the immune system by binding to Zcytor18 ligand, (see page 69, lines 29-35), and can be used therapeutically.

While, the instant specification asserts that the polypeptide encoded by the claimed nucleic acid can be used therapeutically, and discloses conventional protein and nucleic acid administration techniques, it does not disclose specific diseases which can be treated or diagnosed using the claimed nucleic acid or the encoded polypeptide. The specification establishes no connection between any physiological condition or disorder and this protein, i.e, is the claimed nucleic acid or the encoded polypeptide over expressed, under expressed or completely lacking in any disorder? The specification provides no working examples as to the activity of the polypeptide encoded by the claimed nucleic acid, and one of ordinary skill in the art would not be able to

predict what activity would be possessed by the protein. Therefore, one of ordinary skill in the art would not be able to predict the activity or physiological importance of the polypeptide encoded by the claimed nucleic acid. Another asserted utility for the polypeptide encoded by the claimed nucleic acid is to identify and isolate Zcyor18 ligands, however, using the claimed nucleic acid to produce the encoded protein for research purposes, does not afford the claimed nucleic acid specific, substantial and well established utility, because, a compound to be used as a scientific tool where what is being studied is the material itself, does not appear to be a specific, substantial or well established utility. Furthermore, instant specification does not disclose any information regarding the biological activity or functional data of the protein encoded by the claimed nucleic acid, therefore, one of ordinary skill in the art would not know how to use it to modulate the immune system as applicants have asserted. Yet another asserted utility for the polypeptide encoded by the claimed nucleic acid is to raise antibodies, however, using a protein to generate antibodies does not afford said protein a specific utility since any protein can be used to generate antibodies. Applicants submit an expression pattern for the Zctor18 gene, however, in order for a nucleic acid or the encoded polypeptide to be useful, in differentiating tissues, there must be a disclosed correlation or relationship between the claimed nucleic acid or the encoded polypeptide and a disease or disorder. The presence of the Zcytor18 gene in the stated tissues is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed Zcytor18 gene and a disease. Instant specification discloses that the Zcytor18 gene is higher in breast tissue than in normal breast tissue and that it can be used to differentiate tissues, (see page 3, lines 10), however, it is unclear, whether this gene is higher in breast cancer tissue compared to normal tissue.

The claimed invention is directed to a nucleic acid encoding a polypeptide of as yet undetermined function or biological significance, therefore, unless Applicants demonstrate the physiological significance or the biological role of the instant nucleic acid and the protein it encodes, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

4b. Claims 18-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification does not define the physiological role of the Zcytor18 polypeptide encoded by the claimed nucleic acid, neither does it establish a link between this protein and a disease or a physiological condition. Therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded protein. The specification discloses only the sequence of the claimed nucleic acid and the encoded protein, and that is insufficient to establish a specific or substantial utility for the claimed invention.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5a. Claim 18 is rejected under 35 U.S.C. 102(a) as being anticipated by Bloecker et al (November 1999).

Bloecker et al disclose an isolated polypeptide comprising an amino acid sequence that shares 100% to the instant SEQ ID NO:2, from amino acid residues 336 to 753 and the nucleic acid encoding said polypeptide. See attached copies of the comparison of SEQ ID NO:2 of the instant invention and the sequence of the reference,(SEQUENCE COMPARISON 'A').

Therefore Bloecker et al reference meets the limitation "an isolated nucleic acid encoding a polypeptide comprising an amino acid residues 336 to 753 of SEQ ID NO:2" recited in claim 18 of the instant application.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-

8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
May 23, 2003

Gary A. Kunz
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